

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
93-R-0512

CUSTOMER NO.
39987

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

EXPLORA BIOLABS, L L C
1155 CAMINO DEL MAR, #535
DEL MAR, CA 92014

(658) 351-1900 858-273-6574

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS/sites

(b)(2)High, (b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	6	0	0	36	36
5. Cats					
6. Guinea Pigs	1	0	33	0	33
7. Hamsters					
8. Rabbits	12	0	103	0	103
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

DEC 13 2007 ✓

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

(b)(6), (b)(7)(c)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6), (b)(7)(c)

12/12/07

HEADQUARTERS

(AUG 91)

Column E Explanation

This form is intended as an aid in completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 93-R-0512
2. **Number of animals used in this study:** 36
3. **Species (common name) of animals used in the study:** dog
4. **Explain the procedure producing pain and/or distress.**

These are toxicity studies for pharmaceutical drug development and the toxicities of novel compounds being tested are unknown. Animals will receive either an acute dose (1-4 times a day for 1 day) or repeat dose (1-4 times a day for up to 30 days). Dose administration routes may be orogastric, oral/pill, intravenous bolus injection, intravenous infusion, subcutaneous, intramuscular, ocular/topical, or ocular/intravitreal. Animals may experience toxic side effects from these novel compounds, both transient and prolonged, for which pain and/or distress can not be relieved. Clinical signs suggestive of pain and distress include, but are not limited to: severe inactivity, lethargy, emesis, significant decrease in food consumption, dehydration, weight loss, hypothermia, abnormal behaviors and central nervous system changes (e.g. convulsions, aggression, paralysis, tremors, sleepiness, self-mutilation), difficulty breathing, salivation/lacrimation, obvious bleeding from one or more orifice, blood in urine/feces, diarrhea and hunched posture. Although infrequent, mortality may result due to the severity and duration of one or more of the above-mentioned effects. The attending veterinarian will be consulted on adverse reactions as appropriate. If it is determined that an animal will not recover, or if toxicity is severe, euthanasia will be performed. Examples of criteria that may be used to euthanize animals include, but are not limited to, more than 30% decrease in body weight over a 2-week period and lethargy for more than 3 days. The severity and duration of one or more of the mentioned effects, with consideration of the attending veterinarian consultation, will be used as criteria to euthanize animals.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below.)**

The purpose of these studies is to identify potential toxicities associated with new chemical entities. Depending upon the type of toxicity and its mechanism, the animal may recover or rebound. This type of data is an important finding, and the use of sedatives or pain relieving agents may confound this important data.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):**

Agency: Food and Drug Administration
CFR: 21 CFR 312.23(a)(8)(ii)(a)

DEC 13 2007